

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13099



0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page 1 of 3 CFSAN

Form Approved OMB No 0910-0291 Expires 12/31/94 See OMB statement on reverse

FDA Use Only

Triage unit sequence # 89525
13099

A. Patient information

1. Patient identifier	2. Age at time of event: <u>20</u> or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-----------------------	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) 7-2-98

4. Date of this report (mo/day/yr) 9-9-98

5. Describe event or problem

my son was taking these products from _____ & a few from the drug store. He speed his body up so much. He lost weight & quite sleeping. Had headaches & became very talkative. was admitted to hospital soon diagnose as Psychotic Schizophrenia. was put on strong med. took 30 day to get my son released. Released as Psychotic Schizophrenia. on strong meds. I did not give him meds & he returned to normal. Because of these things he was misdiagnosed. I'm very angry that we as consumers

6. Relevant tests/laboratory data, including dates

we not made more aware that thing sold in _____ etc & health food stores can be harmful if taken in large doses. I myself was diagnosed with migraine headaches

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

This disappear as these thing were stopped

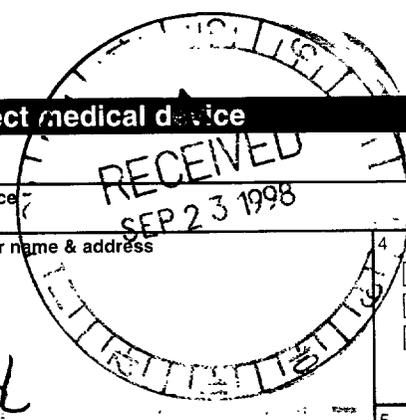
~~CTU~~ "son" - 13099
reporter/"myself" - 13125

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 <u>See list</u>	#1 _____
#2 _____	#2 _____
2. Dose, frequency & route used	4. Diagnosis for use (indication)
#1 <u>2 1/2 months</u>	#1 <u>To Better Health</u>
#2 <u>2-3 times daily</u>	#2 <u>& make Stronger</u>
5. Event abated after use stopped or dose reduced	8. Event reappeared after reintroduction
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 _____	#1 _____
#2 _____	#2 _____
9. NDC # (for product problems only)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

D. Suspect medical device

1. Brand name	4. Operator of device
2. Type of device	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
3. Manufacturer name & address	5. Expiration date (mo/day/yr)
6. Model #	7. If implanted, give date (mo/day/yr)
catalog #	8. If explanted, give date (mo/day/yr)
serial #	9. Device available for evaluation? (Do not send to FDA)
lot #	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)
other #	10. Concomitant medical products and therapy dates (exclude treatment of event)



E. Reporter (see confidentiality section on back)

1. Name, address & phone #	2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation <u>Data Entry Operator</u>	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			000001



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent damage

the product caused the

all the details

blems – quality, performance such as:
 mination
 ility
 ents
 r labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-FDA-1088 for VAERS form for vaccines

If your report is a serious adverse event that occurred in a facility, you may be legally required to report to the manufacturer. Please advise the person who should handle such reports.

RECEIVED
 FEDERAL STAMP
 OCTOBER 1-31

Confidentiality: The patient's identity is held in confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS
 Hubert H. Humphrey Building,
 Room 721-B
 200 Independence Avenue, S.W.
 Washington, DC 20201
 ATTN: PRA

and to:
 Office of Management and
 Budget
 Paperwork Reduction Project
 (0910-0230)
 Washington, DC 20503

Please do NOT return this form to either of these addresses.

FDA Form 3500-back

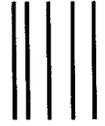
Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services

Public Health Service
 Food and Drug Administration
 Rockville, MD 20857

Official Business
 Penalty for Private Use \$300

BUSINESS REPLY MAIL
 FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD
 POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION



NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO



MEDWATCH

The FDA Medical Products Reporting Program
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20852-9787

000002

SEP 25 10:52 AM '98

RECEIVED
 CLINICAL RESEARCH & REVIEW/OSH HFS-452



1. DHEA: dehydroepiandrosterone 50mg Vitamin C 15mg

2. HydroxyCut:
 Hydroxagen 2000mg
 (supplying 1000mg of hydroxycitric Acid)
 MA Huang Extract 334mg
 (standardized for 6% ephedra)
 Guarana Extract 910mg
 (standardized for 22% Caffeine)
 Willow Bark Extract 100mg
 (standardized for 15% Salicin)
 L-Carnitine 100mg
 Chromium Picolinate 300mg

3. Mini Two-way Action: Mini Thins
 25 mg Ephedrine HCl
 200 mg Guafifensin

4. PRO RX
 Vitamin A, C, D, E, Thiamin, Riboflavin, Niacin
 Vitamin B-6, Folic Acid, B-12
 Biotin, Pantothenic Acid, Phosphorus,
 Iodine, Magnesium, Zinc, Copper,
 Potassium Sodium Protein,
 Phenylalanine

5. Amino Fuel, L-Carnitine & Branched Chain
 Amino Acids
 Protein Amino Acids, ^{15g} Carbohydrates, 10g
 L-Alanine - 1200mg L-Arginine 1100, L-Aspartic Acid - 1240mg
 L-Carnitine - 25mg L-Cystine 919mg, Glycine 3200mg
 L-Glutamic Acid 2040mg, L-Histidine - 460mg
 L-Isoleucine 230 L-Leucine 900, L-Lysine, L-methionine
 Phenylalanine 400mg, Proline 2130, 000003
 L-Serine 540mg, L-Threonine 480mg
 L-Tryptophan 82mg L-Tyrosine 200mg L-Valine

The eight essential Amino Acids

The L-tryptophan

B-1, B-2, B-3, B-6 - B-12

Pantothenic Acid, Folic Acid Biotin

PABA Choline Bitartrate

Inositol,

Q1

Diet System

CitriMax (Garcinia) 1500 mg

Kola Nut 550 mg

Guarana Extract 100 mg

Chromium Picolinate 300 mg

Choline Bitartrate 100 mg

Betaine HCL 25 mg

L-Carnitine Complex 300 mg

7

Golden Seal Root

000004

89525

CFSAN

September 9, 1998

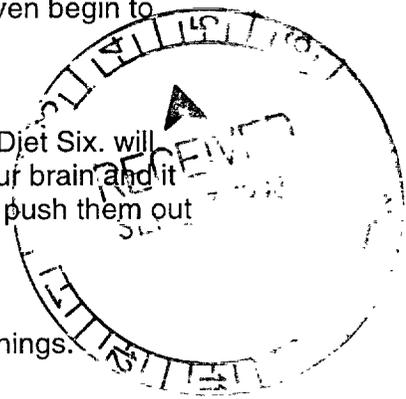
My son had been taking several different drinks from [REDACTED] Some things were also purchased at the local drug store. He had gotten into the health program real heavy. Wanting to improve myself as well I also was on several of the health improvements. He was drinking some of these drinks 3-4 times a day sometimes more. Thinking that these thing were healthy because the has vitamins and other thing good for the body. As in fact they came from a health food store. More strength more energy and to look good is a plus. So all in all it would make sense that since these thing were good for you and healthy that they are harmless. How far from the truth can this be? Let me tell You. For myself I was diagnosed with migraine headaches. At this point in time I did not contribute it to these drinks and pills. They were good for you. My son keep on until he lost about 20 lbs and was sleeping 2-3 hours a night. Eventually he was not sleeping at all and a lose of appetite. After several day of no sleep no food and talking 90 miles a minute and his thought were getting confused. I took him to a doctor and explained what was going on. He in turn sent us to a hospital. My son ended up in a hospital for 30 day and was put on strong drugs which he had adverse reaction to. I spent 30 days trying to prove his sanity. He was diagnosed as Psychosis Schizophrenia which he is not never has been and hopefully never will be. To get him out of this place I had to promise to keep him on this medication & make an appointment with a Psychiatric doctor who could also prescribe medication. When I got him home I did not give him the medicine because I knew what had happened to him. He had speed his self up on these drinks. I realized also that they were the cause of my little episode. Being off the Halloo, Olanzapine, Verapasmil and cogentin. his doctor can find nothing wrong with him. The thing is if I had not known what had cause my sons reaction I would have kept him on the medication and he would be a nonproductive person today. He was suppose to stay on the medicine for the rest of his life. I feel that the general public needs to be made aware that just because you purchase something in a Health Food Store does not mean it is good for you. The idea of more is better and will make you healthier faster is also a misconception. My Son and I learned the hard way. Please alert the general public as to what can and will happen with these things. My Son was misdiagnosed and could have been dysfunctional for the rest of his life. If I had not done reasearch on these things and took him off of his medication. I can not even begin to describe the pain, heartache, anxiety. We both lost 30 days of our lives.

From my personal experience mixing ephedrine with Amino Fuel and Diet Six. will make you have severe headaches. It feels as if there is a vise around your brain and it is squeezing it . It will make your eyeballs feel as if something is trying to push them out of your head. You will not be able to tolerate noise.

Something needs to be done to educate the general public about these things.

Thank You
[REDACTED]

Home: [REDACTED]
Business: [REDACTED]



REC'D.

SEP 18 1998

MEDWATCH CTU

000005

89525

Adverse Event Questionnaire

Complaint Number: 13099

Investigator: Gen/Mierle

Consumer Information		
Date of Report: <u>03/04/99</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury	
	<input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input checked="" type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC	
Name: [REDACTED]	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M	Age: <u>21</u>
Race: <input checked="" type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown		

Information on Adverse Event	
Date of Adverse Event: 7/1/99 <u>7/2/98</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>HOME</u>
Previous Adverse Effects to Product Type: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <u>7/1/98</u>	

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
See Medical Records

How long did the symptoms last?
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). See Below

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

Did event abate after use of suspected product stopped or dose reduced: Yes No Unknown
 Did symptoms reoccur after reintroduction of suspected product: Yes No Unknown Not Applicable
 Did symptoms reoccur after using other products with the same ingredients: Yes No Unknown Not Applicable

Medical Information
Was a health care provider seen?: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Give health care provider's name, address and telephone number:

Occupation of Health Care Provider: MD Osteopath Naturopath Nurse Pharmacist
 Other (specify)

What medical tests were performed and what were the results? 000006

What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)?

MedWatch #13099 Investigation
ATT # 3 Pg# 1 of 2
4-5 March 1999 GM

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): Yes No

Remarks: Started taking supplements early May 1998.

- ① ^{EARLY May} 25 mg Mini Two way Action w 2 cups Coffee & 300mg ASA. BID/2 wks
- ② - 1wk break "Mini Two-Way Action" Lot# 98F0396 6/00
- ③ - start back w ① / 1 mo
- ④ - Reduced to days when he lifted weights 5 or 6 days wk. Took once or twice day / 2 wks
- ⑤ - started Early May took as labeled "Hydroxycut 4 caps morning & afternoon / 45 days
"Hydroxycut 80 caps 36921/10-99"

Product Category

1. Adverse event attributed to:

Medical Food (under medical supervision) Infant Formula

Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)

Other (traditional food) _____

Other Product Problems

2. Foreign Object
(specify): _____

3. Other (specify): _____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

See

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

Check here if ingredients are unknown

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

Aspartame

Color Additive (please specify) _____

Monosodium Glutamate

Sulfite

Other Ephedrine "Ephedra"

Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire: Yes No Unknown
Product Sample Available: Yes No Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: Yes No

Life-Threatening: Yes No

Hospitalization: Yes No (if YES, indicate if initial or prolonged) 30 days

Required intervention to prevent permanent impairment/damage: Yes No

Did the adverse event result in a congenital anomaly: Yes No

MedWatch #13099 Investigation
ATT # 3 Pg# 2 of 2 GM
4-5 March 1999

000007



FROM THE DESK OF
 Gerald Mierle, Investigator
 Food and Drug Administration

MEMORANDUM

Date: 8 March 1999

From: Gerald Mierle

Subj: MedWatch # 13099 Documents

To: Bridgette M. Wallace, ARMS Monitor, HFS-636

Attached are the Investigational Records of MedWatch # ¹³⁰⁹⁹13009 as requested. The investigation included WedWatch # 13125 also with its records sent under separate cover. The mother of the patient in MedWatch # ~~13009~~ submitted MedWatch # 13125 and # ~~13009~~ ¹³⁰⁹⁹.

All of the records for MedWatch #13099 were collected from the patient's Lawyer [REDACTED]. She is a partner with the firm of:

[REDACTED]

Ms. [REDACTED] has control of the medical records, Nutritional Supplements, and empty containers. She had interviewed the patient in MedWatch # 13099. When I contacted the mother she had referred me to the lawyer's office. Ms. [REDACTED] was informative and copied all of the pertinent medical records in this investigation for the FDA. She also copied the labeling of the "Hydroxycut" and the "Mini Two Way Action" Tablets, both of which contain ephedrine. She also gave 20 tablets of the "Mini Two Way Action" as a sample. Receipt for sample was issued for the sample and documents. Ms. [REDACTED] signed an "Authorization For Medical Records Disclosure" for the patient. The Sample is being held at the [REDACTED] under Lock and Key awaiting determination as to where it should be sent for analysis.

The sample was marketed by: BDI Pharmaceuticals, a division of Body Dynamics, INC A check of the national OEI lists the mfr type for Body Dynamics, Inc. as "D 53" & "L 60", CFN as 1831179, last EI date as 4/28/93 with Inspection conclusion as "A C" with reschedule date of "08/94" Priority "1".

ATTACHMENTS:

1. Assignment dtd November 10, 1998
2. Authorization For Medical Records Disclosure dtd 4 March 1999
3. Adverse Event Questionnaire dtd 4 March 1999



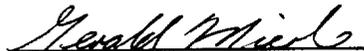
000008

4. FDA 484 Receipt for Sample dtd 4 March 1999

5. OEI Print Screen for Body Dynamics, Inc.

EXHIBITS:

1. Unpurged Medical Records on patient identified in MedWatch # 13099
2. Labeling for "Hydroxycut" lot # 36921 10/99
3. Labeling for "Mini Two Way Action" lot # 98F0396 6/00
4. Confidentiality Statement for [REDACTED] to Law Firm


Gerald Mierle, CSO
[REDACTED]

Distribution:

ORIG: Wallace, HFS-636

CC: Kevin Morrow, BLT-DO, R&E

BLT-DO [REDACTED]

Wallace, HFS-636 (Additional Copy)

000009



FROM THE DESK OF
Gerald Mierle, Investigator
Food and Drug Administration

MEMORANDUM

Corrected Copy

Date: 8 March 1999

From: Gerald Mierle

Subj: MedWatch # 13099 Documents

To: Bridgette M. Wallace, ARMS Monitor, HFS-636

Attached are the Investigational Records of MedWatch # 13099 as requested. The investigation included WedWatch # 13125 also with its records sent under separate cover. The mother of the patient in MedWatch # 13099 submitted MedWatch # 13125 and # 13099.

All of the records for MedWatch #13099 were collected from the patient's Lawyer [REDACTED] She is a partner with the firm of:

[REDACTED]

Ms. [REDACTED] has control of the medical records, Nutritional Supplements, and empty containers. She had interviewed the patient in MedWatch # 13099. When I contacted the mother she had referred me to the lawyer's office. Ms. [REDACTED] was informative and copied all of the pertinent medical records in this investigation for the FDA. She also copied the labeling of the "Hydroxycut" and the "Mini Two Way Action" Tablets, both of which contain ephedrine. She also gave 20 tablets of the "Mini Two Way Action" as a sample. Receipt for sample was issued for the sample and documents. Ms. [REDACTED] signed an "Authorization For Medical Records Disclosure" for the patient. The Sample is being held at the [REDACTED] under Lock and Key awaiting determination as to where it should be sent for analysis.

The sample was marketed by: BDI Pharmaceuticals, a division of Body Dynamics, INC A check of the national OEI lists the mfr type for Body Dynamics, Inc. as "D 53" & "L 60", CFN as 1831179, last EI date as 4/28/93 with Inspection conclusion as "A C" with reschedule date of "08/94" Priority "1".

ATTACHMENTS:

1. Assignment dtd November 10, 1998
2. Authorization For Medical Records Disclosure dtd 4 March 1999
3. Adverse Event Questionnaire dtd 4 March 1999

000010

4. FDA 484 Receipt for Sample dtd 4 March 1999

5. OEI Print Screen for Body Dynamics, Inc.

EXHIBITS:

1. Unpurged Medical Records on patient identified in MedWatch # 13099
2. Labeling for "Hydroxycut" lot # 36921 10/99
3. Labeling for "Mini Two Way Action" lot # 98F0396 6/00
4. Confidentiality Statement for [REDACTED] to Law Firm

Gerald Mierle, CSO
[REDACTED]

Distribution:

ORIG: Wallace, HFS-636

CC: Kevin Morrow, BLT-DO, R&E

BLT-DO, [REDACTED]

Wallace, HFS-636 (Additional Copy)

000011



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Telephone: [REDACTED]
FAX: [REDACTED]

Date: 27 May 1999

To: Constance Hardy, CFSAN

Subject: Memorandums on MedWatch Numbers 13099 & 13125

From: Gerald Mierle, CSO

As per our conversation of 27 May 1999, the following items are addressed:

1. The missing memorandum for MedWatch 13125 has been sent by e-mail attachment thru Banyan.
2. The memorandum for MedWatch 13099 had errors listing the MedWatch number 13099 as 13009. The correct number is 13099. The corrected memorandum also is being sent as an attachment with the above mentioned Banyan message.
3. The labeling for Hydroxycut was included in the collection report # 27459. There was no physical sample of the medication (nutritional supplement) to be collected.

Gerald Mierle, CSO
[REDACTED]

000012